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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/664,171

09/16/2003

Michi Garrison

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IP PROSECUTION DEPARTMENT  
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IRVINE, CA 92614-2558

EXAMINER

WITCZAK, CATHERINE

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

08/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/664,171	<b>Applicant(s)</b> GARRISON ET AL.	
	<b>Examiner</b> Catherine N. Witczak	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-21 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 1-5, 7-21 and 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*Wm* 8/18/07

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claim 2 is rejected under 35 U.S.C. 102(e) as being anticipated by Gordon et al (2002/0188253). Gordon et al disclose in Figure 9 a catheter system comprising catheter (98) and a catheter/guidewire (96) having compliant balloons (80 and 86) slidably housed together.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3, 4, 7, 8, 9, 13, 15, 17-20, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al in view of Gordon et al.

Claims 1, 3, 8, 9, 13, 18, and 19: Gordon et al disclose in Figure 9 a catheter system with two slidably housed catheters both having occlusion devices. The catheter system of Figure 9 does not disclose expressly show the second catheter being provided with a pressure monitor port and pressure regulator

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proximal of the second expandable occlusion device and open to the isolated interior segment between the first and second occlusion devices. Gordon et al however disclose in Figure 1 and in paragraph 0047 that it is known to use a pressure monitor port (74) and pressure regulator (28) between two occluding devices. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify embodiment of Gordon et al as shown in Figure 9 with a pressure monitor port and pressure regulator between the two occluding devices as taught in the embodiment of Figure 1, since such a modification would allow the pressure in the isolated segment to be monitored and regulated.

Claims 4, 15, 20, 22 and 23: Gordon et al disclose in Figure 9 the second catheter being spaced from the inner wall of the first catheter to create a coaxial infusion lumen (100) surrounding the second catheter.

Claims 7 and 17: Gordon et al disclose in Figure 9 the system comprising an infusion port (92).

3. Claims 5 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al in view of Baker et al (US 2002/0026217).

Gordon et al disclose the claimed invention except for the second catheter having three lumens with the centrally located lumen provided with an axially extending tube. Baker et al teach that it is known to use a trilumen catheter with an axially extending tube disposed within the centrally located lumen as set forth in Figure 3 to provide a catheter with additional lumens which may be used for additional infusion devices or other purposes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Gordon et al with a trilumen catheter with an axially extending tube disposed with the centrally located lumen as taught by Baker et al, since such a modification would provide a catheter with additional lumens which could be used for additional infusion devices or other purposes.

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4. Claims 10 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al as in view of Machold et al (2004/0024437).

Gordon et al disclose the claimed invention except for the pressure regulator comprising a spring controlled reservoir. Machold et al teach that it is known to use spring controlled reservoir in paragraph 0081. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Gordon et al with pressure regulator comprising a spring controlled reservoir as taught by Machold et al, since such a modification would provide the system with a inexpensive, reliable pressure regulator.

5. Claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al as in view of Preissman et al (US 5728063).

Gordon et al disclose the claimed invention except for one of the catheters having a relatively stiff proximal region, a softer intermediate region and a still softer distal region. Preissman et al teach that it is known to use a relatively stiff proximal region, a softer intermediate region, and a still softer distal region in column 3, lines 17-31 to provide sufficient flexibility to permit access to tortuous regions while retaining sufficient tensile, column, and hoop strengths to enhance resistance to kinking and collapse (column 2, lines 2-6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Gordon et al with a catheter with a relatively stiff proximal region, a softer intermediate region and a still softer distal region as taught by Preissman, since such a modification would provide the system with a catheter having a relatively stiff proximal region, a softer intermediate region and a still softer distal region for providing sufficient flexibility to permit access to the tortuous regions while retaining sufficient tensile, column, and hoop strengths to enhance resistance to kinking and collapse.

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*Response to Arguments*

Applicant's arguments filed 6/12/2007 have been fully considered but they are not persuasive. Applicant argues that the inner tubular member of Gordon (96) is not a guidewire. However, even though Gordon may refer to element 96 as a catheter, the device of Gordon meets all the claims limitations of the Applicant's application, and furthermore, there is nothing in the Applicant's claims which would prevent Gordon's element 96 from being used as a guidewire.

*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witczak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cw

*8/18/08*

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*